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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,405	09/30/2005	Andrea Cossarizza	COSSARIZZA-1	5546

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER

STAPLES, MARK

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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01/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/522,405		COSSARIZZA, ANDREA	
	Examiner		Art Unit	
	Mark Staples		1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☒ Claim(s) 1 and 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/06/2008</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Applicant's amendment of claims 1 and 24 in the paper filed on 11/06/2008 is acknowledged.

Claims 1-24 are pending and at issue.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections that are Withdrawn

Claim Rejections Withdrawn - 35 USC § 112 Second Paragraph

2. The rejection of claims 1-24 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements is withdrawn. Applicant has amended the claims to recite the structural cooperative relationships of the fluorescently labeled probes of the sequences NucSeqI, NucSeqII, NucSeqI', and/or NucSeqII'.

3. The rejection of claims 1-24 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is withdrawn, as Applicant has amended the claims to provide the essential steps to carry out the claimed methods.

Rejections that are Maintained

Claim Rejections Maintained - 35 USC § 112 First Paragraph

4. The rejection of claims 1-24 under 35 U.S.C. 112, first paragraph is maintained. Applicant's central argument that the claims are enabled as written is not persuasive.

Applicant has amended the base claims to recite probes with quenchers and fluorophore which are enabled by the specification. Thus Applicant has overcome that part of the rejection for prior claims only reciting the fluorophore and omitting the essential quencher.

Applicant's central argument in regards to being able to determine copy number from weights or concentrations of weight per volume by following the claimed methods is not persuasive. The central argument is that by knowing the concentration of the probes, the molar concentrations of the probes can be determined by one of ordinary skill in the art and hence copy number can be determined as the molar concentration here is an expression of copy number per unit volume. However the claims do not recite this essential element.

Applicant's evidence (references cited on the IDS filed on 11/06/2008) supports Applicant's argument in part that the state of the art pre- and post- filing of the claimed invention enable determining copy number from weights or concentrations of weight per unit volume, provided a relationship is known between either the weight or concentrations of weight per unit volume and copy number. However, to be found allowable, an appropriate and specific recitation is needed in the claims (as supported by the originally filed specification) that incorporates this essential element of linking weights or concentrations of weights per unit volume to copy number. One general

possibility that might be considered is that the CN as recited can be corrected based on relative probe weights (when the probe weights are unequal).

The equation for CN (Copy Number) as currently recited in each of claims 1 and 24 is erroneous. And although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

As the claims are still not enabled for the recited equation for CN, the rejection is maintained.

New Objections and Rejections Necessitated by Amendment

New Claim Objections

5. Claim 1 is objected to because of the following informalities: line 4 repeats “NucSeqI” in the expression “NucSeqI and NucSeqI”. It appears that “NucSeqI and NucSeqI’ ” is intended. Appropriate correction is required.
6. Claim 2 is objected to because of the following informalities: an amendment of the claim is indicated by the underlining of the colon while the status of the claim is indicated as “previously presented”. Appropriate correction is required.

Prior Art

7. No prior art was found which teaches or fairly suggests a nucleic acid amplification technique that uses two nucleic acid sequences on a single vector as controls to determine the relative copy number ratio of two corresponding nucleic acid

sequences. The closest prior art found was Ginzinger et al. (2002), Zhang et al. (1997), and Gibson et al. (1996) each of whom teach use of known nucleic acid sequences to determine relative copy numbers of unknown nucleic acid sequences. However, none of Ginzinger et al. (2002), Zhang et al. (1997), or Gibson et al. (1996) teach or fairly suggest a control or standard which has two nucleic acid sequences on a single vector.

Conclusion

8. No claim is allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples

/M. S./

Examiner, Art Unit 1637

January 17, 2009

/Kenneth R Horlick/

Primary Examiner, Art Unit 1637